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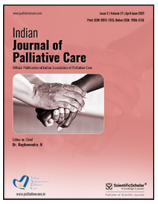

*Original Article*

# Developing a Screening Tool for Serious Health-related Suffering for Low- and Middle-Income Countries – Phase-1: Domain Identification and Item Generation

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## ABSTRACT

**Objectives:** The Lancet Commission on Global Access to Palliative Care and Pain Relief reported significant levels of health-related suffering globally, with the highest incidence in the low- and middle-income countries. The report describes suffering as health-related when it is associated with illness or injury of any kind and suffering as serious when it cannot be relieved without professional intervention and when it compromises physical, social, spiritual, and/or emotional functioning. This paper describes the preliminary development phase of a tool for screening Serious Health-related Suffering (SHS) at individual patient level, suitable to the healthcare settings in India. The study was conducted by the National Cancer Grid-India, with support from the Indian Association of Palliative Care.

**Materials and Methods:** Domain identification and item generation were conducted according to the recommendations for tool development by the American Psychological Association and World Health Organisation quality of life instrument. The consensus for domain questions and associated items was achieved using Delphi, nominal group technique, expert review, and polling.

**Results:** The Phase-1 study for developing the screening tool for SHS contextualised to resource-limited settings generated a bilevel questionnaire. The initial level assesses and scores the physical, emotional, social, spiritual, and financial domains of health-related suffering. The next level assesses seriousness, through functional limitation and patient's preference.

**Conclusion:** The generation of domains, items, and screening questions for health-related suffering and its seriousness completes the preliminary phase of developing the SHS screening tool applicable to a resource-limited healthcare setting. Field testing of the tool is being conducted as Phase-2 of this study, to validate it in clinical settings.

**Keywords:** Serious health-related suffering, Global health, Health-services accessibility/organisation and administration, Palliative care/organisation and administration, Universal health insurance, Organisation and administration

## INTRODUCTION

Suffering is an aversive multidimensional dynamic experience of severe distress, associated with events that potentially threaten the intactness of a person.[1-4] The Lancet Commission on Global Access to Palliative Care and Pain Relief explored the concept of 'health-related suffering' as its central precept. It used an innovative conceptual framework to describe the global prevalence of 'serious health-related suffering' (SHS) from a population perspective.[5] Approximately 61 million adults experienced SHS globally in the year 2015, and 80% of them were from low- and middle-income countries (LMICs).[5,6] It is estimated that 21.3 million patients experience SHS in LMIC alone, and 7.2 million of them are Indians.[7] Moreover, 2.5 million

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children die with SHS every year and 98% of them belong to LMICs.[5]

The Lancet report highlights SHS across the physical, psychological, spiritual, and social domains, as a crucial, unrecognised, and unmet care need. It also recommends an essential package for the physical and emotional domains of the SHS, to help mitigate the suffering, strengthen the national health systems, and meet the sustainable development goals of universal health coverage.[5]

Alleviating suffering is the goal of healthcare and the central tenet of palliative care.[8,9] Recently, the International Association for Hospice and Palliative Care (IAHPC) published a consensus-based definition of palliative care in terms of SHS, which includes its assessment and management at physical, psychological, spiritual, and social levels.[9] Identification of this multidimensional experience of SHS at an individual level is imperative to its evaluation and management.[10] It is challenging to capture a subjective phenomenon like SHS, as the experience of suffering under similar conditions may be different amongst individuals.[11] Although a qualitative interview might be more appropriate to explore suffering at an individual level, a screening tool would be a more direct and practical strategy in a time and resource-constrained setting. The ideal tool should be able to measure the multidimensional subjective elements of suffering, be brief, simple, meaningful, and not trigger emotional distress.[12,13] This research was necessitated, as no screening tools for SHS were identified during the scoping search of the literature, for reasons elaborated under the discussions section.

Cancer is recognised as a significant contributor to SHS.[5] The National Cancer Grid of India (NCG) is a collaborative network of cancer care organisations, research institutions, patient groups, and professional societies, funded by the Government of India with the mandate of facilitating uniform standards of cancer care.[14] Based on the evidence for health-related suffering reported by the Lancet Commission, the NCG-India, with support from the Indian Association of Palliative Care, initiated the process of developing a screening tool to assess SHS at an individual patient level, appropriate for resource-constrained settings.

### Aims and objectives

The study aim is domain identification and item generation for the SHS screening tool framework. The larger purpose of developing this tool is in coherence with the recommendations of the Lancet Commission, which is to strengthen the capacity of healthcare centres in resource-constrained settings in LMICs to identify SHS wherever relevant and activate access of patients to essential care packages – medicines, equipment, and human resources.[5]

## MATERIALS AND METHODS

Overview: Domain identification and item generation were done according to prescribed recommendations for tool development.[15-17] The initial draft contents, domains, and items are based on the elucidation of key concepts; 'health-related suffering' and 'its seriousness' as defined in the Lancet report. The draft tool content then underwent consensus evolving techniques; the Delphi process, nominal group technique (NGT), and expert review. To enhance its robustness and achieve concurrence, the transparent expert consultation (TEC) process with an online ranking of tool versions was used additionally [Figure 1].[16,18] Details of the methodology are described below.

### Concept clarification and development of the tool content

Concept clarification required critical thinking, to reflect the defined realm of SHS authentically, when developing the tool with its domains and items.[19] The initial premise for the SHS concept was entrenched in the Lancet Report and the definitions of palliative care and health by the WHO and the IAHPC [Appendix-1 supplementary files].[5,20,21] The Lancet report identified physical, emotional, social, and spiritual realms of suffering, and the initial draft tool incorporated these four domains.[22] Items for each domain were developed iteratively using an interpretive process.[23] The initial draft tool, with domains, and items scored on a Likert scoring system underwent the consensus development methods.[24]

### Content adequacy through consensus building

The Delphi process was the first level consensus evolving technique.[25] Eighty experts, who either experienced suffering or engaged professionally with the suffering of cancer patients from across India, were invited to participate. The forty who responded and participated were a heterogeneous group of doctors, nurses, medical social workers, psychologists, patients, family caregivers, hospital administrators, and medical students. The Delphi rounds were conducted, using a web-based survey platform, interspersed with controlled feedback to obtain and synthesise the views of the panel. Participants received a set of documents with (i) introduction, context, objectives of the tool and clinical settings for implementation, (ii) instructions for the Delphi process, (iii) draft tool, and (iv) privacy policy and contact for clarifications. The responses from two rounds of Delphi were collated and categorised as: (a) Comments on agreement or disagreement and (b) suggestions for modifications on; domains, the structuring of the questionnaire, item pool, and the scoring system.

The revised tool post-Delphi with recommendations was handed over to the nominal group for review and recommendations.[24] Eleven participants of the NGT discussed the tool content to achieve consensus. A senior palliative care researcher familiar with NGT facilitated the discussions. The group reviewed the draft tool focused on the conceptual underpinning, structure, and style of domain questions, the items, and the scoring system. The NGT discussion lasted for 200 min and used an open voting system by show of hands for draft revision. Besides approving the

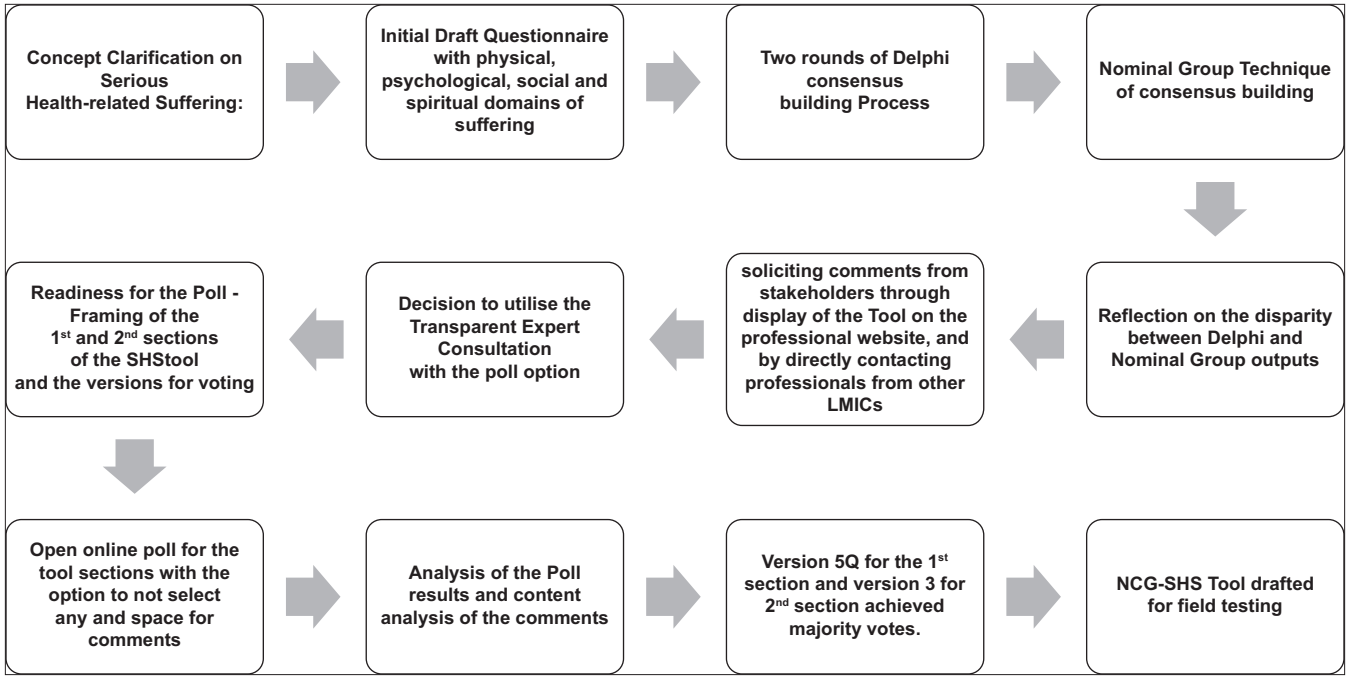


**Figure 1:** The sequential methodological steps used to build consensus on the National Cancer Grid of India-serious health-related suffering screening tool.

general structure and contents of the draft, the expert group recommended replacing the spiritual domain with financial, as they considered financial distress to be highly contextual to SHS in a resource-constrained setting. They also proposed changing some of the descriptors along with the modification of the scoring system with an overall score of >2, to improve the sensitivity of the screening tool.

### Interim appraisal and additional methodology

The discrepancy in tool domains between Delphi and NGT outcomes necessitated a reflective review by the study team. The Lancet report featured the spiritual domain of suffering as one of its four domains, and this was ratified by the Delphi panel. However, the nominal group recommended replacing it with a financial domain, considering financial toxicity as a significant contributor to health-related suffering in a resource-constrained setting.[26,27] The nature of divergence in domains identified during the consensus-building process was acknowledged. Next, the NCG website displayed the redrafted tool for 3 months, for public suggestions and comments. Feedback from independent external reviewers was also accessed. The excerpts of comments received from the website and those obtained from external reviewers are listed in [Appendix-2 of the supplementary files].

Based on the interim appraisal of suggestions and feedback at this stage, the research team conceded both spiritual and financial domains to be significant and relevant to the suffering of patients in a resource-limited healthcare setting [Appendix-3 of the supplementary files].[28-30] The team decided to enhance the methodological rigour, and test concurrence with earlier recommendations, by applying the poll option of Transparent Expert Consultation to the study.[18]

The poll explored two critical aspects of the tool. The first was to identify applicable domains. Three versions of the tool were developed; 3Q, 4Q, and 5Q, representing different combinations of the domains. The score of ≥2, to indicate the presence of health-related suffering, was a uniform feature across all versions. The second aspect was to incorporate appropriate features to determine the 'seriousness' of the health-related suffering in the questionnaire tool, in congruence with its definition. The poll on this aspect also had three versions to choose from; (i) a score ≥2 as adequate in itself; (ii) patient's seeking additional professional help as a binomial yes or no and (iii) impact of the suffering on functional capacities, as a binomial yes or no.[31] Poll participants had an option to not select any of the versions and to post their views and suggestions on the tool.[24] The open online polling link was disseminated using the official networks of NCG-India and the Indian Association of Palliative Care, newsletters, and social media. Members of the Delphi and NGT were also invited to participate. The poll remained open for three months. The data were collected using Google Forms and analysed through Microsoft Excel. The frequency analysis is depicted through bar and pie charts.

## RESULTS

Among the 282 poll participants, palliative care physicians formed 40.78% of voters, followed by 17.38% specialist oncologists and 10.99% nurses with a smaller representation from social workers, counsellors, medical students, patients, and family members. Southern states of India contributed 41.13% votes, with a smaller percentage from the west (19.15%), north (17.02%), north-east (10.99%), east (8.51%), and central (2.13%) states [Appendix-4 of the supplementary file].

About 65.3% of the poll participants voted for the 5Q version of the tool with five questions representing physical, psychological, social, spiritual, and financial domains. 4Q version received 17.38% and 3Q received 14.18% of the votes, respectively. Moreover, 52.8% of participants felt that impact of suffering on functional capacities determined its seriousness, while 34.40% of selected patients wish for additional help to determine the seriousness of health-related suffering [Appendix-5 of the supplementary file]. Eighty-three participants posted comments.

[Table 1] depicts the content analysis performed on the comments provided by poll participants. This allowed for fine tuning and simplification of the terminologies and descriptors of the domains and items. For example, the item 'breathlessness' was replaced by 'breathing difficulty,' and 'depression' was replaced by 'feeling sad.' The voting and comments helped determine tool content to screen for 'seriousness,' once a score of ≥2 suggested the presence of health-related suffering.

The NCG-SHS tool developed through this study has two sections, as shown in [Table 2]. The initial section has questions related to the five domains of health-related suffering, with a 3-point scoring system on a Likert scale with values of 0 (Not at all), 1 (A little), and 2 (A lot) overall, for each domain. A total score of ≥2 indicates that the patient has health-related suffering. The latter section determines the seriousness of the suffering by checking for (i) functional limitation of at least 14 days over the past 30 days and (ii) the patient's felt need to seek additional professional help. Screening positive for SHS required a score of ≥2 in the 1st section along with a 'yes' to either or both questions of the latter section.

## DISCUSSION

This article narrates the development methodology and drafting of a novel tool to measure SHS suitable to LMICs. Evidence suggests that SHS among cancer decedents will increase (2016–2060) more quickly in low- and lower-middle-income countries compared to upper-middle- and high-income countries. Hence, this study to develop the NCG-SHS screening tool is timely, relevant, and in response to the critical need to identify, evaluate and respond to the multidimensional health-related suffering at individual patient level.[32]

Four out of the five domains included in the NCG-SHS tool have ample evidence as contributors to SHS.[5,8,9] The fifth domain that is, suffering due to financial toxicities, was identified as a distinct domain during this study, as a majority of health-related expenditure in India is out-of-pocket.

To make the domain questions easy to understand, they are supported by item descriptors. For example, the 1st domain question is – *Associated with your health, do you suffer physically?* Here, the item descriptors orient the patient to suffering due to their physical concerns. The scoring for all domains is kept simple; as, 'not at all,' 'a little' or 'a lot' based on the patient's perception of suffering in that domain. A score of ≥2, will trigger second level enquiry for seriousness.

For the social, spiritual, and financial domains, the questions are worded carefully. For example, if the spiritual domain question had been formulated as, *Associated with your health, do you suffer spiritually?*, patients may/may not comprehend the scope and extent of that domain. The current phrasing of this domain question without the word 'spiritual', but with its accompanying descriptors items; 'feeling punished/fearful/shame/guilty/angry with God/no meaning in life/feeling disconnected,' clarifies the intent of the domain more clearly.

Cancer with its chronic fluctuating illness trajectory interspersed with relapses and complications demands high-cost treatment and result in catastrophic out-of-pocket expenses and healthcare-related poverty. Accordingly, the financial domain of suffering is incorporated as contextual to India (and other LMICs). Again, this domain question does not contain the word 'financial,' which can limit the scope of this question to treatment affordability of the patient/family. Instead, the item descriptors allude to the negative impact that ill-health and treatment may have had on their economic self-sufficiency, such as, loss of employment, interruption of studies, new loan, debt, sold property or assets, or migration to access treatment etc. When financial associated suffering is recognised, it can activate an early referral to the social worker and align patient/families to the available resources as per their eligibility for example, (a) state/central government schemes (support for travel for treatment), (b) patient welfare funds of the institution and (c) access to educational or vocational training/support programs (for eligible family members) and assist toward economic self-sufficiency of patients/family members, including educational support for affected children. Unveiling financial toxicity as an important contributor to suffering could pre-empt the oncology team toward proportionate cost-beneficence of offered therapies. This can also avoid deepening sense of guilt/helplessness for the patient/family.

Although there are no existing gold standards tool to compare the SHS tool, the distress thermometer (DT), the Edmonton Symptom Assessment System (ESAS), and the integrated Palliative care Outcome Scale (iPOS) have been used in Indian settings, to identify symptoms and distress of

**Table 1:** Content analysis of poll survey data.

| **Content Analysis of Poll Survey Data**<br>**Specific suggestions and comments from eighty three poll participants helped fine-tune the framing and contents of the NCG-SHS screening Tool.** | |
|---|---|
| **Representative quotes and comments** | **Rationale to acknowledge and reflect upon** |
| Addition of Financial related Suffering | |
| "While financial distress might add to social and spiritual sufferings, listing them as a separate and equal parameter might skew the results. For example, people with "a little" financial difficulties only need one more suffering to trigger the next step, but people without would need two suffering categories to trigger". | 'A little financial distress' and 'a little anxiety'- would qualify as 'health-related suffering, but it will screen positive for 'serious' health-related suffering, only if it limits/prevent the person from doing what s/he wishes to do. If in fact, these two 'are preventing/limiting' functions this we feel needs to be acknowledged/addressed. |
| Comprehensiveness of symptoms | |
| The Lancet Report listed 11 physical and 4 psychological as the main symptoms of SHS; would it be good to incorporate those in their simpler forms, to the tool? | This suggestion has been accepted to align with the Report. Provision of 'other issues' within the items pool, provides scope for addition of extra symptoms. |
| Likert Scale related | |
| "3 point scale is not helpful. Many might be having problems in between" | The tool had begun with a 5 point Likert but simplified to 3 point after expert review and comments, which suggested that the middle range scores in 5 point scale i.e., 'a little', 'quite a bit' and 'very much' were difficult for the patient to distinguish. |
| "always a tendency for patients to opt for the middle one… unsure about the correctness of the response" | |
| '*The three-point scoring system has the advantage of simplicity. But there is the possibility that patients tend to go for the easy option of choosing the middle one. Of course, as a screening tool, it may not have much significance*' | Minimizing this unsure middle range added also to the simplicity of the tool. |
| *Graded scoring system better than binary approach*<br>*Different scores should trigger different responses*<br>*Different scoring system for each domain* | These suggestions were Not included, for maintaining the simplicity of the tool. |
| On using the Total score of>2 indicating presence of health-related suffering | |
| *'Cut off score appears to be very low, I think for our scenario and patient load, 5 or more will be better.'* | The context being for screening, the tool required high sensitivity over specificity.<br>The tool assigned a total score>2 as indicative of the 'presence of health-related suffering', and not as indicative of 'serious' suffering. |
| "*if the base line is 2 then it seems to be a presupposed plan to include almost 99% of patients as SHS*" | Choice of this low total score was to safeguard the sensitivity of the screening tool, so that a score of 2 that indicated "A lot" of suffering, albeit in one domain may be picked by this Tool. |
| *"I think in preliminary screening 1+1 + 1 need not trigger though >/= (any 2) +1 should trigger".* | Also, a score>2, entails further screening for 'seriousness' based on the functional limitation. This additional step will likely ensure that the highly sensitive Tool does not lose its validity as a 'non-discriminator'. |
| *While a 5-point assessment can be more elaborate, maintaining the same scoring, I.e. 2 or higher, it is probably going to label most as in high distress* | As an example, the opportunity to respond to a patient who is unable to walk for>14 days over the last 30 Days (functional limitation) due to 'a lot' of pain (score 2 in physical domain), would be lost, if a high score is stipulated to recognize suffering.<br>And yet, if there is 'a little' pain (score 1 in physical domain) and there is 'a little' sadness (score 1 in emotional domain) and if it does not limit functioning, the patient is screened negative for SHS. |
| *It is not clear whether "a little" and "a lot" are measurements of intensity or frequency. If it is intensity, would that overlap with the second question of limit on function? If it is frequency, would it be clearer with quantifiable scale such as "more than 2 times a week"?* | Since suffering is an experience, we planned to leave the basis of grading it open to the patient's perception. When a patient answers 'a lot' it may mean intensity, frequency, or both. "A lot" may mean; some suffering incessantly OR it may also mean high suffering whenever it happens. Either way, it would be significant to the patient. Moreover, field testing would allow monitoring for confounding factors. |

*(Contd...)*

**Table 1:** *(Continued).*

| **Content Analysis of Poll Survey Data**<br>**Specific suggestions and comments from eighty three poll participants helped fine-tune the framing and contents of the NCG-SHS screening Tool.** | |
|---|---|
| **Representative quotes and comments** | **Rationale to acknowledge and reflect upon** |
| Adequacy of processes for responding to score>2<br>*'If possible, responding to significant SHS version 2 and 3 can be combined for a better result'*<br>*'It would be good to combine the 2nd and 3rd versions. ask if the concern limited functioning and ask if he/she needs help'*<br>*'With physical symptoms E.g. Breathlessness- do we need requirement of 14 days of functional limitation to screen in? What if the onset of symptoms is since 3-5 days and the score is 3?* | These comments expressed the poll results to an extent. While Version-3, with functional incapacity to detect 'seriousness' led the poll (52.5%); more than 1/3rd of voters chose version 2, with 'patient's preference for extra care'(34.9%).<br>The NCG-SHS Tool has integrated these suggestions. In addition, the Tool gives equal weightage to the impact on functions as well as to the patient's preference. We believe this improves its strength as a screening Tool for subjective suffering. |
| Terminology in the Tool – Health Vs. Ill health<br>*Will it be better if it asks "Associated with your present health" instead of ill health?* | As this is in alignment with the definition and concept of 'health' related suffering, the NCG-SHS Tool has integrated this suggestion– [Table 2] |
| Output documentation of the SHS-Tool<br>*What will be documented prominently on the case file? SHS>2? Or "Patient has got SHS"* | The score of<2 is documented as no SHS. If the answer to either question in the second section is ☑ "Yes', then the output is documented as SHS .<br>The patients preference on seeking additional help is also documented to respect subjective impact of the concern. |
| These concepts will be reviewed based on the phase-2 of the study, after the Field Test. | |

patients. The DT elicits the subjective distress score in cancer patients under multiple domains. However, the contributors to distress are not all health-related.[33] Furthermore, DT is not linked to an essential care package. ESAS is a patient-centred symptom assessment tool that documents the presence and severity of nine physical/emotional symptoms, along with the sense of wellbeing, which is quick and easy to administer, interpret and report.[34] However, the sum of its unidimensional scores may not represent the multidimensional experience of suffering in an individual. Two patients with the same ESAS score for pain may have a different perception of suffering due to that pain. The iPOS evaluates care needs and monitors care outcomes within a palliative care setting.[35] However, significant limitations of iPOS as a screening tool for SHS are that (i) the contents do not represent SHS domains relevant to India, (ii) the competencies to administer and analyse iPOS as a screening tool in the rushed oncology settings in India are low and (iii) the time factor, as iPOS on an average, requires >10 min to complete. Moreover, none of these tools explore the patient's awareness of the suffering and their perceived need for additional professional help.

The NCG-SHS tool appraises the domains of health-related suffering specific to the resource-constrained healthcare setting, which aligns well with the LMIC context. Moreover, it ensures and respects the patient's perception of the seriousness of suffering and their perceived need for additional professional help. Once validated through field testing, this tool may be used to screen, and trigger detailed evaluation of contributors for planning further care.

### Strengths and limitations

The NCG-SHS tool has emerged independent of diagnosis. The sequential and synchronous application of multiple consensus-building techniques has made the process of domain identification, item generation, and framing of the tool robust. The domains and items of the tool are represented in simple language and encompass common concerns associated with serious illness. The critical reflections and insights of the reviewers and poll participants during this phase have enabled the researchers to fine-tune and contextualise the tool content for the field testing.

The Lancet Commission report emphasises the need for models incorporating care at the core of disease management, integrated from the point of diagnosis. It calls for strong metrics and data to monitor progress and implement research around SHS.[5] The development of tool to screen SHS in individual patients, under the aegis of the large network of NCG-India, is in congruence with this objective, and can serve as a useful metric in this realm for India.

Considering the need to use the tool across patient interfaces upstream to palliative care, the homogenous composition of the nominal group consisting of palliative care physicians may have been a limitation. However, the Delphi participants

**Table 2:** The Study output – The NCG - SHS screening Tool

| **NCG - SHS Tool for Field Testing** | | | | |
|---|---|---|---|---|
| **NCG-SHS-Tool Section 1- Check for Health-related Suffering** | | | | |
| **Domain-based questions on Health-related Suffering** | **Not at all Score 0** | **A little Score 1** | **A lot Score 2** | **Domain Score** |
| • Associated with your health, do you suffer physically? With pain/breathing difficulty/vomiting/constipation/ weakness/feeding/loose motion/bleeding/itching/ wounds/difficulty with senses (see, hear, smell, touch, taste)/difficulty moving/other issues | | | | P = |
| • Associated with your health, do you suffer emotionally? Feeling sad/unloved/worried/angry/lonely/difficulty sleeping/confused/poor memory/other issues | | | | E = |
| • Associated with your health, do you suffer due to issues with family/relationships/friends/community/feeling isolated/difficulty at work/difficulty with hospital visits/ difficulty communicating/other issues | | | | S = |
| • Associated with your health, do you suffer due to feeling punished/fearful/shame/guilty/angry with God/no meaning in life/disconnected/other issues | | | | Sp = |
| • **Associated with your health, do you suffer due to** lost job/discontinued studies/stopped working/loan/debt/ sold property/sold assets/migrated out/other issues | | | | F = |
| • Is there the Presence of Health-related Suffering? P+E + S+Sp+F | Total Score ≥ 2 | | Total Score < 2 | |
| Domains: P- Physical; E – Emotional; S – Relations/Social; Sp – Spiritual; F- Financial | | | | |
| **Total Score < 2 → No SHS ☒ The screening for SHS is continued at pre-decided intervals, as per the Institutional policy** | | | | |
| **Total Score ≥ 2 there is some health-related suffering Check for the seriousness of the health-related suffering by asking questions A & B in the next section** | | | | |
| **NCG-SHS-Tool Section 2- Check for Seriousness of the Health-related Suffering** | | | | |
| A) Has this suffering limited you from doing what you need to do, for >14 days over the last 30 days? e.g., self-care (feed, bathe, dress, walk, toilet); care for others; communicate; learn/think/perform duties; sleep/rest? Yes / No | B) Do you seek additional professional help for these concerns? Yes / No | | | |
| Responses to questions from the 2nd section | **Screening Outcome to be recorded on the Case Sheet** | | | |
| 1. ☐ YES, to both A and B Notify the treating team so they may evaluate further and activate essential care-pathways as decided by the administration | SHS ☑ | | Seeks Help ☑ | |
| 2. ☐ NO to A and YES to B Notify the treating team, so they may evaluate further and activate essential care-pathways as decided by the administration. | SHS ☑ | | Seeks Help ☑ | |
| 3. ☐ YES, to A and NO to B Educate patient/family about the support available and encourage to access help when they need. Empower with information. | SHS ☑ | | Seeks Help ☒ | |
| 4. ☐ NO to both A and B The screening for SHS is continued at pre-decided intervals, as per the Institutional policy. | SHS ☒ | | Seeks Help ☒ | |

and voters of the poll were a diverse group, comprising palliative care providers, oncologists, healthcare providers from other disciplines, and members of the public. The method of open voting by show of hands might have caused a bias; a secret ballot could have avoided this. The multicentric field testing of the tool planned as Phase-2 of the study will help evaluate perspectives of the most relevant of all stakeholders, the patients.[36]

### Future considerations

As mentioned, the next phase of this study will evaluate the psychometric properties of the NCG-SHS tool through a multicentric field test for validity and reliability, feasibility, relevance, sensitivity, and acceptability.[13] A cognitive interview of the patient with a psychologist (oriented to SHS concept) has been identified as the relevant standard for validation of the tool during Phase-2. After validation, the tool can be studied for application in other languages. As the tool is independent of diagnosis, it could also be validated and adapted for patient interphases in other disease settings as well.

Appendix-6 of the supplementary file compares the rate of people with SHS in cancer for India with a few other LMICs.[1] From their healthcare access Indicators, it may be surmised that this tool may be relevant to LMICs with a socioeconomic and cultural background similar to India.

### Implications on policy, practice, and research

The NCG-SHS tool by early identification of serious suffering in the patient can activate strategies to mitigate them. It can help identify dimensions of illness beyond scans, investigation parameters, and symptoms inventory. Activation of the essential care pathways can enable timely referrals to palliative care, facilitate supportive care, communications, timely access to the social worker and counselling services, and facilitate transitions in goals of care.[37] Discussions around decision-making in terms of alleviating suffering can align the perspectives of the professional with that of the patient/family. The tool might help uncover areas of deep concern for the patient, which may otherwise be missed. Accordingly, SHS tool could promote therapeutic relationships and shared decision-making.[38,39] All of the above can strengthen the overall care outcomes that are aligned with the best interests and priorities of the patient. Once validated, the NCG-SHS tool can be useful in research, for quantifying outcomes of a complex intervention. Monitoring the tool output at an institution level could also serve as a surrogate indicator of "the robustness" of supportive care services and may inform protocols and policies. Overallthe tool has the potential to" enrich the evidence-based development of caring sciences.[40]

## CONCLUSION

In this paper we have described the process of generation of domains, items and screening questions for health-related suffering and its seriousness during the preliminary phase of developing the SHS screening tool applicable to a resource-limited healthcare setting. Field-testing of the tool is being conducted as phase-2 of this study, to validate it in clinical settings.

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### Authors' contributions

NV, NS, AG, SD, AD and RRR formed the core research team that conceived and designed the project, activated and organised the methodology processes, collected the data, analysed and drafted the manuscript; MRR, as a commissioner of the Lancet Report contributed in the conception and participated in the Nominal Group Technique; SB provided logistical support and CSP provided guidance, administrative permissions, and facilities for the research and contributed to the manuscript and for critical revision of the draft. All authors reviewed and approved the final manuscript.

### Ethics approval and consent for study participation

The study did not involve any direct interactions with patients, patient records, investigative or of behavioural interventions. Hence, ethics approval and consent for study participation were not applicable.

### Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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### Conflicts of interest

There are no conflicts of interest.

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## SUPPLEMENTARY FILE FOR NCG SHS TOOL DEVELOPMENT ARTICLE

### Appendix 1: Concept Clarification

**The concept of health-related suffering for the NCG SHS Tool was rooted in the three definitions listed in this Box.**

**Definition of Suffering in Lancet Report:**

- Suffering is health-related when it is associated with illness or injury of any kind.
- Suffering is serious when it cannot be relieved without medical intervention and when it compromises physical, social or emotional functioning

**WHO Definition of Palliative Care**

Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.

**Palliative Care Definition by the International Association for Hospice and Palliative Care (IAHPC)**

Palliative care is the active holistic care of individuals across all ages with 'serious health-related suffering' due to severe illness, and especially of those near the end of life. It aims to improve the quality of life of patients, their families and their caregivers.

Palliative care:

- Includes, prevention, early identification, comprehensive assessment and management of physical issues, including pain and other distressing symptoms, psychological distress, spiritual distress and social needs. Whenever possible, these interventions must be evidence based.
- Provides support to help patients live as fully as possible until death by facilitating effective communication, helping them and their families determine goals of care.
- Is applicable throughout the course of an illness, according to the patient's needs.
- Is provided in conjunction with disease modifying therapies whenever needed.
- May positively influence the course of illness.
- Intends neither to hasten nor postpone death, affirms life, and recognizes dying as a natural process.
- Provides support to the family and the caregivers during the patient's illness, and in their own bereavement.
- Is delivered recognizing and respecting the cultural values and beliefs of the patient and the family.
- Is applicable throughout all health care settings (place of residence and institutions) and in all levels (primary to tertiary).
- Can be provided by professionals with basic palliative care training.
- Requires specialist palliative care with a multi-professional team for referral of complex cases.

**WHO definition of health**

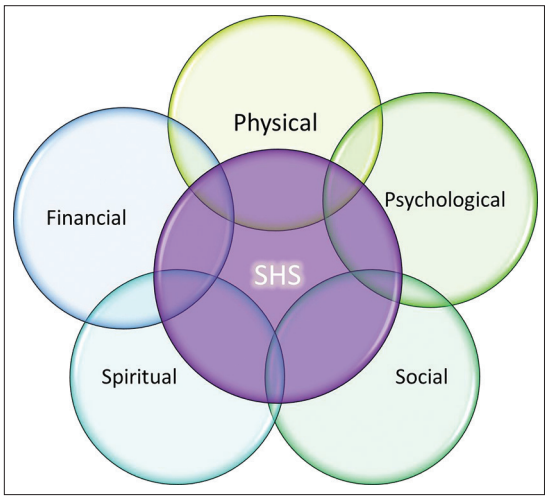
Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.

**Appendix 2: Excerpts of comments after website display and external reviews.**

**These comments post Delphi and NGT, informed revision of terminologies used in the SHS Screening Tool during the interim analysis.**

1. *It is difficult to differentiate the middle scores in the Likert five score version – e.g., "very much" and "intolerable".*
2. *My concern is that the tool will identify nearly everybody and will thus be a non-discriminator.*
3. *Health-related financial suffering is real in India. But using the word 'financial' in the tool may trigger expectations that something may be done to benefit the patient financially, e.g., relief from further payment of charges. It would be useful to capture emotional responses to events such as discontinuing studies, discontinuing work, forced migration, mortgage etc., that expresses financial setbacks indirectly, and yet with a scope for counselling or resolutions.*
4. *"Generally, I agree with the tool. My concern is only related to question 2 (the emotional domain), where you have listed conditions, with medical terms such as depression or anxiety, instead I would use sadness, sleeping/concentration problems. Then it is more at the same level with other questions."*
5. "*I think item 3 should address social concerns separately from practical concerns instead of joining them together*
6. *"Question for the individual completing this item should be separate from the family member experiencing the financial issues".*
7. *A total Score > = 2* triggering reference to Care Unit/team as decided by the institution is appropriate
8. *Suggest to simplify scoring - from 5 point to 3 point scoring - This may be easier to use by health assistants, clerks and by patients/family where; Score 0 - Not True OR Hardly ever True; Score 1- somewhat true OR Sometimes True and; Score 2 - Very true, Mostly true OR Always True.*
9. *A three-point scoring system with 'Not at all', 'A little' and 'A lot' may be a more direct way of scoring suffering*

**Appendix 3: Domains of Serious Health-related Suffering as depicted in the NCG-SHS Tool. The additional fifth domain i.e. financial-related suffering may be unique to LMIC settings, where the insurance coverage is low and public health-funding to support healthcare costs are low.**



**Appendix 4: The Designation and geographic distribution of poll participants**

| | |
|---|---|
| Palliative Care Physician | 40.78% |
| Physician, Oncologist | 17.38% |
| Nurse | 10.99% |
| Other | 8.87% |
| Administrator, Program Manager | 4.61% |
| Medical Social worker | 4.61% |
| Care coordinator, volunteer | 3.19% |
| Counselor, Psychologist | 2.84% |
| Medical student | 2.84% |
| Family, friend, personal care giver | 1.42% |
| Patient | 1.06% |
| Educationist, researcher | 1.06% |
| Rehabilitation specialist | 0.35% |
| **Total** | **100.00%** |

| | |
|---|---|
| South | 41.13% |
| West | 19.15% |
| North | 17.02% |
| North East | 10.99% |
| East | 8.51% |
| Central | 2.13% |
| Outside India | 1.06% |
| **Total** | **100.00%** |

**Appendix 5: Poll Results with percentage of votes cast**

**4 A – Poll Results for concurrence with the basic premise for the Tool**
**4 B - Poll Results for the three versions of the NCG-SHS Tool – 3 Q, 4 Q, and 5 Q**
**4 C – Poll Results for the three versions of the response to total score >2**


Figure 4 A

Concurrence for the Basic Premise for developing the Tool

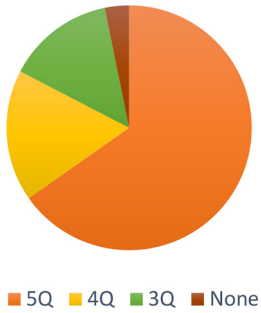



Figure 4 B

Poll results for the first section to determine domains to identify and score health-related suffering

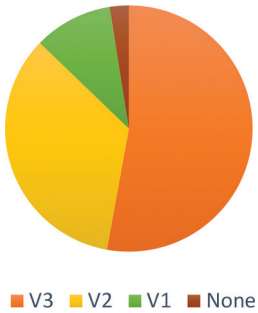



Figure 4 C

Poll results for the second section to determine seriousness of the health-related suffering

**Appendix 6: Comparison of the Rate of people with cancer-related Serious health-related Suffering, and healthcare access indicators for India, Low Middle Income Countries (LMIC) and USA representing High-Income countries Group (HIC)). The Tool may be relevant in LMICs with socio-economic and cultural background similar to India.**

| Indicators | India | Ghana | Pakistan | Bangladesh | Egypt | Philippines | Nepal | Myanmar | USA |
|---|---|---|---|---|---|---|---|---|---|
| Classification by Income Group^ | | | LMICs | | | | | | HIC |
| Health Expenditure as % of GDP* | 3.53 (2017) | 3.26 (2017) | 2.90 (2017) | 2.27 (2017) | 5.29 (2017) | 4.45 (2017) | 5.55 (2017) | 4.66 (2017) | 17.06 (2017) |
| Rate of People with SHS for Cancer (in thousands)^^ | 0.994 | 0.734 | 0.991 | 1.021 | 1.385 | 1.122 | 0.967 | 1.673 | 3.127 |
| Hospital Beds (per 10,000 population)# | 5.3 (2017) | 9 (2011) | 6.3 (2017) | 7.95 (2016) | 14.3 (2017) | 9.9 (2017) | 3 (2012) | 10.44 (2017) | 28.7 (2017) |

^The World Bank Data: The World Bank: Low and middle income. https://data.worldbank.org/income-level/low-and-middle-income?view=chart
*Reference for country level data: Global Health Expenditure Database: World Health Organization: Current health expenditure (% of GDP). https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS
^^Reference for country level data: Global Data Platform To Calculate SHS And Palliative Care Need – Serious Health-related Suffering Database 2015 - https://hospicecare.com/what-we-do/resources/global-data-platform-to-calculate-shs-and-palliative-care-need/database/
#Reference for country level data: Global Health Observatory: World Health Organization: World Health Data Platform/GHO/Indicators: Hospital beds (per 10000 population) https://www.who.int/data/gho/data/indicators/indicator-details/GHO/hospital-beds-(per-10-000-population)